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| APPLICATION NO.                   | NO. FILING DATE |            | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-----------------------------------|-----------------|------------|--------------------------|-------------------------|------------------|
| 09/830,741                        | 06              | /21/2001   | Elmar-Reinhold Burchardt | LE A 33 256             | 2024             |
| 7                                 | 7590            | 06/25/2003 |                          |                         |                  |
| Jeffrey M Gro                     |                 |            | EXAMINER                 |                         |                  |
| Bayer Corporation 400 Morgan Lane |                 |            |                          | RUSSEL, JEFFREY E       | EFFREY E         |
| West Haven, C                     | T 06516         | •          |                          | ART UNIT                | PAPER NUMBER     |
|                                   |                 |            |                          | 1654                    |                  |
|                                   |                 |            |                          | DATE MAILED: 06/25/2003 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | <u> </u>  |          |
|---|--|---|----------|
| 2- '  | Application No.  | Applicant(s)  |          |
|   | 09/830,741   | BURCHARDT ET AL.  |          |
| <ul> <li>Office Action Summary</li> </ul>   | Examiner   | Art Unit  |          |
|   | Jeffrey E. Russel  | 1654  |          |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet w  | vith the correspondence address -   |          |
| A SHORTENED STATUTORY PERIOD FOR REPLY  | Y IS SET TO EXPIRE 3 I   | MONTH(S) FROM   |          |
| THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period volume - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status | 36(a). In no event, however, may a<br>y within the statutory minimum of th<br>vill apply and will expire SIX (6) MC<br>, cause the application to become A | reply be timely filed  rty (30) days will be considered timely.  NTHS from the mailing date of this communical  BANDONED (35 U.S.C. § 133). | ation.   |
| 1) Responsive to communication(s) filed on 27 A   | August 2001 and 28 May   | <u>2002</u> .   |          |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ Th  | is action is non-final.  |   |          |
| 3) Since this application is in condition for allowated in accordance with the practice under   |  |   | ts is    |
| Disposition of Claims   | p.a  | ,   |          |
| 4) $\square$ Claim(s) <u>1-4</u> is/are pending in the application.   |  |   |          |
| 4a) Of the above claim(s) is/are withdraw   | vn from consideration.   |   |          |
| 5)⊠ Claim(s) <u>1 and 4</u> is/are allowed.   |  |   |          |
| 6)⊠ Claim(s) <u>2 and 3</u> is/are rejected.  |  |   |          |
| 7) Claim(s) is/are objected to.   |  |   |          |
| 8) Claim(s) are subject to restriction and/or   | r election requirement.  |   |          |
| Application Papers  |  |   |          |
| 9) The specification is objected to by the Examine  |  | 11 butha Funnina  |          |
| 10) ☐ The drawing(s) filed on 21 June 2001 is/are: a)[  |  |   |          |
| Applicant may not request that any objection to the 11) The proposed drawing correction filed on  |  |   |          |
| If approved, corrected drawings are required in rep   |  | disapproved by the Examiner.  |          |
| 12) The oath or declaration is objected to by the Ex  |  |   |          |
| Priority under 35 U.S.C. §§ 119 and 120   |  |   |          |
| 13) △ Acknowledgment is made of a claim for foreign   | priority under 35 U.S.C.   | § 119(a)-(d) or (f).  |          |
| a)⊠ All b)□ Some * c)□ None of:   | , <b>,</b> , , , , , , , , , , , , , , , , ,   | 0 (, (, (,  |          |
| 1. Certified copies of the priority documents   | s have been received.  |   |          |
| 2. Certified copies of the priority documents   |  | Application No  |          |
| 3. Copies of the certified copies of the prior application from the International But   | nity documents have bee<br>reau (PCT Rule 17.2(a)).  | n received in this National Stage   |          |
| * See the attached detailed Office action for a list  | ·  |   |          |
| 14) Acknowledgment is made of a claim for domestic  |  |   | ation).  |
| <ul> <li>a)  The translation of the foreign language pro</li> <li>15) Acknowledgment is made of a claim for domesting</li> </ul>  |  |   |          |
| Attachment(s)   |  |   |          |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5   | 5) Notice of   | Summary (PTO-413) Paper No(s)<br>Informal Patent Application (PTO-152)  | <u> </u> |
|   |  |   |          |

Application/Control Number: 09/830,741

Art Unit: 1654

- 1. The Sequence Listing filed February 26, 2002 has been approved.
- The abstract of the disclosure is objected to because it is insufficiently detailed with respect to the particular therapeutic uses of the phosphinate peptide analogs. Correction is required. See MPEP § 608.01(b).
- 3. The disclosure is objected to because of the following informalities: A Brief Description of the Drawings is missing from the specification (see 37 CFR 1.74), or possibly such a heading needs to be inserted at page 12, line 6, of the specification. The beginning parenthesis at page 3, line 17, and the end bracket at page 3, line 19, are unmatched. A SEQ ID NO needs to be inserted after the amino acid sequence at page 8, lines 20-21. See 37 CFR 1.821(d). Also, in the sequence, the residue abbreviation "Gln" is misspelled. At page 14, line 10, the end parenthesis after "phenylethyl" is unmatched. Appropriate correction is required.
- 4. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 3 are contradictory because the formulas recited therein require a particular stereoconfiguration, but then the last line of each claim indicates that alternative stereoisomers and enantiomers can be used. It is not clear if the compounds to be used in these claims are to be limited to any stereoconfiguration or not. If not, it is not clear how dependent claim 2 differs in scope from independent claim 1.
- 5. Claims 1 and 4 are allowed. Claims 2 and 3 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action. While the prior art of record teaches the active agents required by Applicants' claimed methods (see, e.g., references R1 and R20 of Applicants' Information Disclosure Statements),

last paragraph), but does not provide any indication or reasonable expectation that the compounds described therein would themselves be useful in the therapeutic treatment of any

disease involving a member of the astacin family.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

June 24, 2003